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EXAMINER	
QIAN, CELINE X	
ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,635	KENYON ET AL.	
	Examiner	Art Unit	
	CELINE X. QIAN	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6,8,10-23,25-27,31-33,46,50,53 and 60-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,8,10-23,25-27,31-33,46,50,53 and 60-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-3, 5, 6, 8, 10-23, 25-27, 31-33, 46, 50, 53, 60-62 are pending in the application.

This Office Action is in response to the Amendment filed on 5/12/08.

Response to Amendment

Acknowledgement is made of the submission of the amended specification. The objection to the specification has been withdrawn in view of the amendment.

The objection to claims 1-33, 46, 50-53 has been withdrawn in light of the amendment.

The rejection of claims 7, 11, 21-33, 51 and 52 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of the amendment.

The rejection of claims 1-3, 5, 6, 8, 10-23, 25-27, 31-33, 46, 50, 53, 60-62 under 35 U.S.C. 112 1st paragraph is maintained for reason set forth of the record mailed on 1/10/08 and further discussed below. This rejection is moot to canceled claims 4, 7, 9, 24, 28-30, 51 and 52, and includes newly added claims 60-62.

Claims 8 and 13 are rejected for new matter for reason given below.

Claim 12 is rejected under 112 2nd paragraph for reason given below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5, 6, 8, 10-23, 25-27, 31-33, 46, 50, 53, 60-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The

claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is re-written to address the amendment.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. Claims 1, 21 and 62 recite a polypeptide encoded by a nucleic acid that hybridizes under stringent condition to T22G5.2 clone, with recited hybridization conditions. Claims 46, 60 and 61 recite a polypeptide has 95% identity to the Ibp-7 polypeptide in Table 3 and 6. The claimed genus of polypeptide encompasses a large number of polypeptide with various sizes and function because nucleic acid hybridizes to

T22G5.2 clone only need to share some sequence homology with T22G.2, and such nucleic acid may encode polypeptide of different function than lbp-7 (encoded by T22G5.2). The lbp-7 is listed in the Table 3, 6 and 8 of the specification for genes with aging function in different genetic background (Table 3 and 8) and a list of class 2 genes (Table 6) with aging function. The specification discloses that lbp-7 is differently regulated in daf2 or daf16 genetic background in C. elegans, being upregulated when daf16 activity is inhibited and is downregulated when daf2 activity is inhibited, and asserting that lbp-7 is a candidate gene for shortened life span. However, while the specification also discloses other genes in this category, the specification fails to disclose whether polypeptide sharing sequence homology with lbp-7 up to 95% is also differentially regulated in same manner as lbp-7 in C. elegans. Similarly, the specification also fails to disclose whether polypeptides encoded by a nucleic acid that hybridized under stringent conditions as recited to the complement of T22G5.2 nucleic acid are also regulated in the same manner as lbp-7. While the skilled artisan is able to identify the genus of nucleic acids hybridize to T22G5.2 and polypeptides having 95% homology with lbp-7, whether these polypeptides sharing 95% homology with lbp-7 or encoded by nucleic acids hybridize under stringent condition as recited would be differentially regulated in the same manner as lbp-7 in C. elegan is unpredictable because neither prior art nor the specification teaches such variants, and thus the structural functional relationship is missing. A search of the prior art reveals only limited information regarding lbp-7, which teaches that T22G5.2 is expressed at a lower level in daf-/- mutants. However, this does not remedy the deficiency of the instant specification for fail to provide sufficient description for the claimed genus of polypeptide that are used to identify a compound that modulates aging. Since the specification only discloses the lbp-7 polypeptide

encoded by the sequence of T22G5.2 is a candidate gene for shortened lifespan in C. elegans without teaching what structure/sequence of the T22G5.2 is important for such function, or which activity of lbp-7 is responsible for such function and its corresponding structure, it would have been hard for a skilled artisan to envision the structure of the lbp-7 which is responsible for the life shorten function. As such, the method of using the claimed genus of polypeptides to identify compound that modulates aging lack adequate description because the specification does not provide sufficient description to this genus of polypeptides. Thus, the specification thus fails to describe the claimed genus by a representative number of species by their complete structure, nor other identifying characteristics to demonstrate Applicants had possession of the claimed invention at the time the application was filed. Therefore, the written description requirement is maintained.

Response to Arguments

In response to this rejection, Applicants argue that the specification as filed disclose the functional characteristics of the encoded lbp-7 protein, which is disclosed in Tables 3, 6 and 8 that describes lbp-7 as a fatty acid binding protein, and the expression of T22G5.2 is regulated in an age dependent manner. The specification also teaches that T22G5.2 is decreased in daf2-mutants of C. elegans, and upregulated in a daf2- and daf16- double mutant. Applicants further argue that hybridization condition is stringent which limit the number of sequences that can hybridize to the full length of the recited T22G5.2 nucleic acid. Applicants assert that claims 3, 5, 22, 23, 61 and 62 should not be rejected because functional requirements are not recited in these claims. Applicants further assert that the disclosure of every single gene or amino acid sequence is not required by the written description requirement because other distinguishing

characteristics can be used to describe a nucleic acid or amino acid sequence. Applicants assert that T22G5.2 nucleic acid and the encoded lbp-7 polypeptide are from C. elegans, whose genome was sequenced and published in 1998 and the sequences can be found in databases. Applicants assert that using this publicly available sequence information and the specification, the skilled artisan would recognize that the inventors had possession of the invention at the time of filing. Applicants further indicate that the present application provides the first evidence that T22G5.2 gene and its encoded lbp-7 protein regulate aging, and the claims are directed to methods of identifying modulators of aging by identifying modulators of the lbp-7 protein activity or expression. Applicants reason that since the structures of the T22G5.2 nucleic acid sequence and the lbp-7 amino acid sequence were known at the time of filing, the written description requirement is met.

Furthermore, Applicants assert that claims 46, 60 and 61 and dependent claims that recite specified percent identity to a reference sequence comport with the Revised Written Description Training materials issued in March 25, 2008. Applicants refer to example 11A to demonstrate that the claimed method in claims 46, 60 and 61 satisfy the Written Description Requirement. Applicants also refer to example 6 of the training material to demonstrate that claims 1, 21 and 62 satisfy the written description guideline, and conclude that the amended claims all have sufficient description from the instant specification.

The above arguments have been fully considered but deemed unpersuasive. The reason for the claimed invention that lack adequate description is set forth in the previous office action and reiterated above with regard to the amendment. With regard to the argument of the disclosed function of lbp-7, Applicants are reminded that the alleged function of the claimed genus of the

nucleic acids and the polypeptides encoded by such nucleic acids need to be related with the structure/sequence of the nucleic acids or polypeptides. Otherwise, a skilled artisan would not be able to envision the common structure of the claimed nucleic acids or polypeptides based on the alleged function of said nucleic acids or polypeptides. In the instant case, while nucleic acids hybridizes under stringent condition to the nucleic acid of T22G5.2 is limited in number by homology to said sequence, they still encompass a great number of nucleic acids of varying lengths which potentially can hybridize to any part of the 22254 base pair T22G5.2 sequence. The specification alleges that T22G5.2 encodes lbp-7 which binds fatty acid and is differentially regulated in daf2 and daf2daf16 mutants. However, it is unclear which part or domain lbp-7 is responsible for fatty acid binding function, and which part or domain is necessary for regulating aging in C. elegans, or whether these domain(s) are same or different. The specification further fails to provide nucleic acids or polypeptides that share homology with T22G5.2 or lbp-7 which has the same alleged function. While not every species needs to be described to satisfy the written description requirement, the specification still needs to provide adequate description of characteristics which can make a skilled artisan be able to identify the structure of the claimed genus of nucleic acids or polypeptides based on the alleged function. Without such information (no description in specification and not known in the art), whether altering any amino acid sequence of lbp-7 or part of the sequence from T22G5.2 that encodes any part of the lbp-7 would still retain both alleged function of the lbp-7 is unpredictable. Thus, the claimed function would not be tied to a unifying structure of the claimed genus of nucleic acids and polypeptides encoded by said nucleic acids. Since the instant claims are drawn to a method of identifying a compound that modulates aging using the claimed genus of nucleic acids and polypeptides

encoded by said nucleic acids, but not nucleic acids or polypeptides themselves, the function of the claimed genus of nucleic acids and polypeptides encoded by said nucleic acids is required in order to practice the claimed method. As such, although claims 3, 5, 22, 23, 61 and 62 do not recite functional requirements of the nucleic acids or polypeptides, the written description analysis needs to include the function of said nucleic acids and polypeptides because it is required to perform the method of identifying a compound that modulates aging. For this reason, the above claims are also rejected for lack of description. With regard to the argument based on public availability of the C. elegan sequence T22G5.2 and lbp-7, Applicants are reminded again that it is not sufficient to have possession of the nucleic acid sequences and polypeptide sequences at the time of filing. The structural and functional relationship between the sequences and alleged function is important to satisfy the written description requirement for instant claims because the function of such claimed genus of sequences is required to practice the claimed invention. As discussed above, the specification needs to provide description of either a representative number of species by their complete structure or other relevant identifying characteristics. For reasons given in the previous office action and above, the specification fails to do both. As such, the claimed method lacks adequate description.

With regard to Applicants' argument base on the training materials, Applicants are reminded the examples cited are different from current situation. While both example 11A and 6 are directed to claims drawn to a product, the instant claims are drawn to method of using a product based on the function of the product. Claim 1 in example 11A does not recite the functional limitation to the isolated nucleic acid, whereas the instant claims are drawn to method of using the claimed nucleic acids or polypeptides based on their function. While claims 1-3 in

example 6 do recite the function of a kinase, a kinase is an enzyme well known in the art that posses conserved kinase domain wherein the structure/sequence can be readily identified. As such, the partial sequence in this example is sufficient for the description based on its kinase function. This is not the case for the instant claims. As stated above, the instant claims are drawn to method of using the claimed nucleic acids or polypeptides based on their function, wherein the age modulating function of the claimed lbp-7 polypeptides are not known to tied to any structure/sequence known in the art or described by the specification. As such, a skilled artisan would not be able to envision the structure of the claimed genus of nucleic acids or polypeptides based on the alleged function. Therefore, for reasons given in the previous office action and above, this rejection is maintained and also extend to newly added claims 60-62.

Claims 1-3, 5, 6, 8, 10-23, 25-27, 31-33, 46, 50, 53, 60-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is re-written to address the amendment.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to

make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

The nature of the invention

The nature of the invention is a method for identifying a compound that modulate aging by contacting a test compound with a polypeptide encoded by a nucleic acid that hybridizes under stringent condition to the complement of nucleic acid of T22G5.2, or a host cell that express lbp-7, or a biochemical system that comprises a C. elegans lipid binding protein-7, wherein the lbp-7 has 95% identity to lbp-7 in Tables 3 and 6, and determine the effect of the compound upon the activity or expression of said lbp-7, wherein a difference between the control without the test compound indicates the compound modulates aging. The dependent claims are further drawn to such a method wherein the activity of the lbp-7 is measured by transcription of the nucleic acid, fatty acid binding to the polypeptide, expression of an age associated gene, duration of the lifespan, wherein the host cell is a C. elegans cell, a mouse cell, a rat cell, a human, a whole organism of C. elegans, mouse, rat or human.

The breadth of the claim

The breadth of the claim is very broad. The claimed scope encompasses identifying a compound of any nature by contacting it with a polypeptide encoded by a nucleic acid that hybridizes under stringent condition to the complement of T22G5.2, and determine any type of the functional effect upon the polypeptide. The claimed scope also encompasses identify a compound that is able to modulate aging in any organism.

The teaching of the specification

The teaching of the specification regarding how to identify a compound that modules aging by contacting it to the claimed polypeptide is rather limited. The specification teaches using microarray and other methods to identify genes that changes expression in daf2 or daf16 mutants which prolongs life in C. elegan. The specification discloses class1 and class2 genes which affect the lifespan of C. elegan differently. However, the specification fails to teach what the effect T22G5.2 has in this process is. Although T22G5.2 is listed in Table 3, indicating it is a class 2 gene, whose transcription is decreased in daf2 minus genetic background, but is increased in daf2-daf16- double mutant in C. elegans, the specification does not provide an explanation of what roles lbp-7 listed in Table 3 has in the aging process. Even the prior art teaches that lbp-7 is a fatty acid binding polypeptide, the specification does not disclose how the fatty acid binding activity of said polypeptide or its variants having 95% homology would relate to the age modulating function of said polypeptides. Moreover, while it appears that lbp-7 is a downstream target of daf and/or daf16, it is unclear whether changing in the expression of said lbp-7 without daf2 and or daf16 genetic background would result in a difference in aging in C. elegans. In other words, the specification fails to explain how to identify a compound that can modulate aging simply by contacting it to the polypeptide encoded by T22G5.2, lbp-7 or sequence homologous to lbp-7 or a cell that expresses lbp-7. The specification fails to establish a nexus between the functional effect such as fatty acid binding or increased transcription of T22G5.2 to the aging process in C. elegan. Moreover, the specification also fails to teach whether the observed differential regulation of the expression of T22G5.2 in C. elegans is also observed or may be used to predict the same effect in other types of cells or whole organism drastically more complicated than C. elegans, such as mammals even including human beings. Based on the very

limited information provided in the instant specification, whether the claimed method may be practiced in any of the cells or organism as claimed is unpredictable. As such, one of skilled in the art would have to rely on the information available in art to practice the method as claimed.

The state of art and level of unpredictability in the art

The state of art at the time of filing is silent with regard to the claimed method. In fact, very little is known about the function of lbp-7, encoded by T22G5.2, with regard to its function in aging. Murphy et al. teach that lbp-7 is a downstream molecule of daf16, whose expression is down-regulated in daf2- C. elegans, whose life is extended than the wild type. However, Murphy et al. do not provide further teaching on how to identify a compound that modulate aging by contacting said compound with a polypeptide encoded by T22G5.2, a nucleic acid having homology with T22G5.2, or whether lbp-7 modulates aging in any other cells or organisms. The prior art also fails to teach any polypeptide encoded by a nucleic acid hybridizable to the T22G5.2 which is related to aging. As discussed above, although C. elegans lbp-7 is differentially regulated in daf2- and daf2-daf16- genetic background whereas the organism appears to have different lifespan, the specification at most teaches that lbp-7 may be downstream target of daf2 and daf16, wherein its direct involvement in aging process is still unpredictable. Moreover, it is unclear what the nexus between its fatty acid binding activity to the alleged aging modulating activity is for this polypeptide. The prior art also fails to indicate how T22G5.2 is related to aging in cells or organisms other than C. elegan. As such, the nexus between those polypeptide and aging is missing. Consequently, whether the polypeptides, cell or organism expressing said polypeptides may be used to identify a test compound of any nature that can modulate aging is unpredictable. In view of very limited teaching from the prior art, it

does not remedy for the lack of guidance of the specification to enable a skilled artisan to practice the method as claimed. Since the prior art does not teach how to identify a compound that modulates aging by simply contact it with a polypeptide encoded by T22G5.2, a cell or organism expresses said lbp-7, and the specification does not teach how to practice the method as claimed, one of skilled in the art would have to engage in undue experimentation to practice the method as claimed. Therefore, the claimed method is not enabled by the instant specification.

Response to Arguments

In response to this rejection, Applicants argue that the amended claims recite that the effect of the compound must be different than a control sample, and the breadth of the claim meets the enablement requirement. Applicants further assert that the specification provides a role for lbp-7 and its encoding nucleic acid for modulating aging, wherein such role is different regulation in daf2 or daf16 background. Applicants assert that Table 8 presents that inhibition of lbp-7 polypeptide expression and activity leads to an increase in lifespan in certain genetic backgrounds, as compared to vector control, and the T22G5.2 specific RNAi molecule is a compound that modulates aging by modulating the activity of expression of the encoded lbp-7 protein. Moreover, Applicants assert that since RNAi negatively regulates its target, it follows that inhibition of the activity of the lbp-7 polypeptide will similarly modulate aging. Applicants thus conclude that the claimed method is enabled by the instant specification.

The above arguments have been fully considered but deemed unpersuasive. The reason for the claimed invention that lack adequate description is set forth in the previous office action and reiterated above with regard to the amendment. With regard to the argument directing to the breadth of the claim, Applicants are reminded that the breadth of the claim is rather broad in

view of the teaching of the specification for reason discussed above. Although the amended claims recite comparison to a control sample, the specification does not set forth what type of effect the skilled artisan should compare, and fails to established the nexus between increased/decreased lifespan in any type of cell or organisms to the expression or a specific activity (such as fatty acid binding) of the lbp-7. While Table 8 discloses T22G5.2 inhibition in C. elegans results in increased lifespan in certain background (nf-3?), it is unclear how this gene product affects aging in wild type C. elegan or other host cell with different genetic background. Further, since the compound of RNAi to T22G5.2 inhibits the expression and activity through decreased expression, whether inhibition of the activity, such as binding of the fatty acid to lbp-7 alone would also increase lifespan of C. elegans is unpredictable. Moreover, the specification also discloses that T22G5.2 is decreased in daf2- mutants with extended lifespan, which appears to indicate that a decrease in T22G5.2 would extend lifespan. This would appear contradict the effect seen in a different genetic background as disclosed in Table 8. The specification also discloses that no single RNAi treatment other than daf16 RNAi itself completely suppressed the lifespan extension of daf2- mutant, indicating that the multiple effecter genes, whose expression is coordinated by daf2 pathway act in a cumulative manner to influence aging because most genes have a relative small effect on lifespan. As discussed in the previous office action and above, the duration of lifespan in different organisms are regulated by a complex pathway which involves many different genes functions in a dynamic manner wherein the evolution from lower organism to higher organism also contributes to the complexity of this network. Based on the teaching of the instant specification of very limited knowledge of lbp-7 in certain mutant strain of C. elegans to extend or shorten lifespan, whether this polypeptide or its homologues can

modulate aging in C. elegans of different background is unpredictable. Further, whether this polypeptide or its homologues can modulate aging in other types of cells or organisms which has entirely different genetic background from C. elegans is also unpredictable. As such, one of skilled in the art would have engage in undue experimentation to practice the claimed method of identifying compounds that modulates aging in any cells or organisms of any genetic background using a cell expressing lbp-7 or its homologue, or simply the polypeptide of lbp-7 or its homologue sharing 95% identity. Therefore, for reason set forth in the previous office action and above. This rejection is maintained.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

Claims 8 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 8 and 13 recite determined an effect of the compound on the lbp-7 fatty acid binding activity to determine whether age is modulated by said compound. This newly added limitation is not supported by the specification. In other words, while the specification discloses measuring age associated effect of a compound, it does not specify the effect is the fatty acid binding activity, and the specification also fails to describe how the fatty acid binding activity of

lbp-7 is related to aging in a cell or organism. Therefore, such newly added limitation constitutes new matter which is not supported by the specification as filed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "wherein the cell that expresses lbp-7 polypeptide is a C. elegans, mouse, rat, or human" renders the claim indefinite because it is unclear how a single cell may be an organism such as mouse, rat or human.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /
Primary Examiner, Art Unit 1636